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10/527,829	11/20/2007	Noriko Ogawa	12218/53	4581

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EXAMINER	
BOYKIN, TERRESSA M	
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1796	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/527,829	OGAWA ET AL.	
	Examiner	Art Unit	
	Terressa M. Boykin	1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10-19-06; 7-10-06; 6-14-05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

- Note that all responses to this action should be sent to Art Unit 1796 .

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Abstract missing and/or mislabeled

This application contains an abstract of the disclosure as required by 37 CFR 1.72(b). filed 3-14-05 which appears to correct the insufficiencies of the abstract filed also on 3-14-05. However on 2-14-08 a notice labeled as the abstract but stated as DO/EO worksheet has been filed. Correction of filing a new abstract or the correction of a filing label is required. Contacting ScanningCustomerSupport@USPTO.Gov is suggested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-13 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 97/23549 see claims; or USP 5213976 see col. 3 line 64 – col. 4 line 47, examples and claims; WO 97/07229 see abstract; or US Patent 6087471 see abstract, cols. 1-6.

WO 97/23549 discloses the invention as follows:

This invention relates to processes for producing a shaped object of polyhydroxyalkanoate (PHA) that makes it possible to omit the preliminary extrusion-compounding step, thus saving expense and limiting loss of molecular weight. The process comprises producing a biomass containing particles of PHA and non-PHA cell material (NPCM), separating the NPCM, suspending the PHA particles in water, agglomerating the suspended PHA particles to a suitable weight average particle diameter, separating the agglomerated PHA particles from the suspension, drying the agglomerated PHA particles, and hot shaping the dry, agglomerated PHA particles. In one embodiment, the weight average particle diameter is 50 μm to 5000 μm. In another embodiment, a plasticiser is added to the agglomerated PHA particles.

USP 5213976 discloses a process for extracting polyhydroxyalkanoates from the cell material of microorganisms by adding an organic solvent for the polyhydroxyalkanoate which is immiscible with water and which has a boiling point of below 100° C., and, if appropriate, by adding water; stirring the resulting extraction mixture, if appropriate with refluxing; separating off the aqueous phase which contains the cell material in undissolved form from the organic phase; and injecting the organic phase into hot water, causing the dissolved polyhydroxyalkanoate to precipitate and the organic solvent to evaporate, and also isolating the precipitated polyhydroxyalkanoate flocs.

WO 97/07229 which is disclosed as follows:

The present invention relates to a process for separating polyhydroxyalkanoate (PHA) from a biomass comprising the PHA, the process comprising: (a) treating the biomass with a PHA solvent and a marginal nonsolvent for PHA; (b) removing any insoluble biomass, thereby leaving behind a solution of PHA and marginal nonsolvent for PHA; and (c) removing the PHA solvent from the solution, thereby resulting in a suspension of precipitated PHA in the marginal nonsolvent for PHA. Optionally, the process further comprises removing the marginal nonsolvent for PHA, thereby leaving behind the PHA. The present invention further relates to the suspension and the PHA produced by the process.

US Patent 6087471 discloses a method of recovering PHA from biomass comprising: providing biomass containing PHA;dissolving the PHA with an effective PHA-poor solvent typically at a temperature above the boiling point of the PHA-poor solvent to produce PHA-enriched solvent and residual biomass materials; separating the residual biomass materials from the PHA-enriched solvent;
reducing the temperature of the PHA-enriched solvent such that PHA precipitation occurs; and recovering the precipitated PHA polymer.

An effective PHA-poor solvent comprises a non-halogenated solvent which preferably dissolves less than about 1% (w/v) of the PHA being extracted at a temperature less than the solvent boiling point. Suitable PHA-poor solvents can be selected from the group consisting of linear and branched R_1 --OH alcohols and R_2 --$COOR_3$ esters where R_1 =C_1 -C_4, R_2 =H or C_1 -C_3, and R_3 =C_1 -C_5. Examples of preferred PHA-poor solvents

include methanol, ethanol, n-propanol, iso-propanol, and n-butanol.

The PHA is dissolved with a solvent mixture comprising a PHA-good solvent and a PHA-poor solvent at a temperature effective for dissolving the PHA, typically at a temperature above about 80° C. The PHA is then precipitated by reducing the temperature of the PHA-enriched solvent.

Suitable PHA-good solvents for use in this aspect of the invention can include essentially any solvent effective for solubilizing the PHA of interest. Preferred PHA-good solvents are typically selected from the group consisting of cyclic and acyclic (linear and branched) R'--OH alcohols where R'=C_4 -C_{10}, cyclic and acyclic R"--COOR'" esters where R"=H or C_1 -C_6 and R'"=C_1 -C_7, cyclic and acyclic R"--COOR'" esters where R'=H or C_1 -C_6 and R'"=C_1 -C_7 and wherein at least one oxygen is substituted for at least one carbon in R" or R'", cyclic and acyclic R^1 --CON--$(R^2)_2$ amides where R^1 =H or C_1 -C_6 and R^2 =C_1 -C_6, and cyclic and acyclic R^3 --CO--R^4 ketones where R^3 =C_1 -C_6 and R^4 =C_1 -C_6.

Examples of preferred PHA-good solvents for use in the methods of the present invention include butyl acetate, isobutyl acetate, ethyl lactate, isoamyl acetate, benzyl acetate, 2-methoxy ethyl acetate, tetrahydrofurfuryl acetate, methyl propionate, propyl propionate, butyl propionate, pentyl propionate, butyl butyrate, isobutyl isobutyrate, ethyl butyrate, ethyl valerate, methyl valerate, benzyl benzoate, methyl benzoate, dimethyl succinate, dimethyl glutarate, dimethyl adipate, isobutyl alcohol, 1-butanol, 2-methyl-1-butanol, 3-methyl-1 butanol, 1-pentanol, 3-pentanol, amyl alcohol, allyl alcohol, hexanol, heptanol, octanol, cyclohexanol, 2-ethylhexanol, tetrahydrofurfuryl alcohol, furfuryl alcohol, benzyl alcohol, 2-furaldehyde, methyl isobutyl ketone, methyl ethyl ketone, g-butyrolactone, methyl n-amyl ketone, 5-methyl-2-hexanone, ethyl benzene, 1,3-dimethoxybenzene, cumene, benzaldehyde, 1,2-propanediol, 1,2-diaminopropane, ethylene glycol diethyl ether, 1,2,3-trimethylbenzene, 1,2,4-trimethylbenzene, 1,3-dioxane, 1,4-dioxane, 1-nitropropane, toluene-2,4-diisocyanate, acetic acid, acrylic acid, acetic anhydride, alpha-methylstyrene, acetophenone, toluene, ethylene glycol diacetate, dimethylsulfoxide and propylene carbonate, dimethyl acetamide, dimethyl formamide, or mixtures thereof.

As shown above, each of the references discloses a prepared from the same components as claimed by applicants.

In view of the above, there appears to be no significant difference between the reference(s) and that which is claimed by applicant(s). Any differences not specifically mentioned appear to be conventional. Consequently, the claimed invention cannot be deemed as novel and accordingly is unpatentable.

However, in the interest of expediently continuing prosecution, in the event that applicants' arguments in the response to the concentrations and/or temperature ranges (although not claimed) adequately provide evidence or a reasonable presumption that the above 102 rejection is considered not to have sufficient specificity according to MPEP 2131.03:

2131.03 Anticipation of Ranges

I. A SPECIFIC EXAMPLE IN THE PRIOR ART WHICH IS WITHIN A CLAIMED RANGE ANTICIPATES THE RANGE

"[W]hen, as by a recitation of ranges or otherwise, a claim covers several compositions, the claim is 'anticipated' if *one* of them is in the prior art." *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (citing *In re Petering*, 301 F.2d 676, 682, 133 USPQ 275, 280 (CCPA 1962)) (emphasis in original) (Claims to titanium (Ti) alloy with 0.6-0.9% nickel (Ni) and 0.2-0.4% molybdenum (Mo) were held anticipated by a graph in a Russian article on Ti-Mo-Ni alloys because the graph contained an actual data point corresponding to a Ti alloy containing 0.25% Mo and 0.75% Ni and this composition was within the claimed range of compositions.).

II. PRIOR ART WHICH TEACHES A RANGE OVERLAPPING OR TOUCHING THE CLAIMED RANGE ANTICIPATES IF THE PRIOR ART RANGE DISCLOSES THE CLAIMED RANGE WITH "SUFFICIENT SPECIFICITY"

When the prior art discloses a range which touches or overlaps the claimed range, but no specific examples falling within the claimed range are disclosed, a case by case determination must be made as to anticipation. In order to anticipate the claims, the claimed subject matter must be disclosed in the reference with "sufficient specificity to constitute an anticipation under the statute." What constitutes a "sufficient specificity" is fact dependent. If the claims are directed to a narrow range, and the reference teaches a broad range, depending on the other facts of the case, it may be reasonable to conclude that the narrow range is not disclosed with "sufficient specificity" to constitute an anticipation of the claims. See, e.g., *Atofina v. Great Lakes Chem. Corp*, 441 F.3d 991, 999, 78 USPQ2d 1417, 1423 (Fed. Cir. 2006) wherein the court held that a reference temperature range of 100-500 degrees C did not describe the claimed range of 330-450 degrees C with sufficient specificity to be anticipatory. Further, while there was a slight overlap between the reference's preferred range (150-350 degrees C) and the claimed range, that overlap was not sufficient for anticipation. "[T]he disclosure of a range is no more a disclosure of the end points of the range than it is each of the intermediate points." *Id.* at 1000, 78 USPQ2d at 1424. Any evidence of unexpected results within the narrow range may also render the claims unobvious. The question of "sufficient specificity" is similar to that of "clearly envisaging" a species from a generic teaching. See MPEP § 2131.02. A 35 U.S.C. 102/ 103 combination rejection is permitted if it is unclear if the reference teaches the range with "sufficient specificity." The examiner must, in this case, provide reasons for anticipation as well as a *>reasoned< statement regarding obviousness. *Ex parte Lee*, 31 USPQ2d 1105 (Bd. Pat. App. & Inter. 1993) (expanded Board). For a discussion of the obviousness of ranges see MPEP § 2144.05.

III. PRIOR ART WHICH TEACHES A VALUE OR RANGE THAT IS VERY CLOSE TO, BUT DOES NOT OVERLAP OR TOUCH, THE CLAIMED RANGE DOES NOT ANTICIPATE THE CLAIMED RANGE

"[A]nticipation under § 102 can be found only when the reference discloses exactly what is claimed and that where there are differences between the reference disclosure and the claim, the rejection must be based on § 103 which takes differences into account." *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (Claims to titanium (Ti) alloy with 0.8% nickel (Ni) and 0.3% molybdenum (Mo) were not anticipated by, although they were held obvious over, a graph in a Russian article on Ti-Mo-Ni alloys in which the graph contained an actual data point corresponding to a Ti alloy containing 0.25% Mo and 0.75% Ni.).

, the following rejection under 35 USC § 103

is as follows:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Method of Recovering Polyhydroxyalkanoic Acid, Yan Qing he Oin, Industrial Microbiology, vol. 29. No. 2 pages 43-47 in view of WO 97/23549 see claims.

With regard to claim 1 **Qing et al.** discloses an agglomerated poly-3-hydroxyalkanoic acid suspension prepared from the same components as claimed by applicants except for using particles as apposed to a solution. However, it would have been obvious for one of ordinary skill in the art at the time the invention was made to use the coagulates as disclosed in WO 97/23549 since discloses a method for producing PHA particles.

With regard to claims 2-4 **Qing et al.** discloses the claimed invention except for the particular selection of two species of monomers of poly-3-hydroxyakanoic acid. However, it would have been obvious for one of ordinary skill in the art at the time the invention was made to PHA since no such unobvious product results therefrom.

With regard to claim 5 **Qing et al.** discloses the claimed invention except for the PHA being produced by a microorganism. However, it would have been obvious for one of ordinary skill in the art at the time the invention was made to use microorganisms since **WO 97/23549** does disclose that bacterium may be used.

With regard to claims 6-9 **Qing et al.** discloses the claimed invention except for the particular selection of the microorganisms used to make poly-3-hydroxyakanoic acid. However, it would have been obvious for one of ordinary skill in the art at the time the invention was made to PHA since no such unobvious product results therefrom and since **WO 97/23549** does disclose that bacterium may be used.

With regard to claim 10 **Qing et al.** discloses the claimed invention except for the particular steps of stirring the suspension and solubilizing cell substances by adding an alkali simultaneously. However, it would have been obvious for one of ordinary skill in the art at the time the invention was made to employ the steps as claimed since **WO 97/23549** discloses on page 43 col. 2 and pages 44 col. 1 the process as claimed. Although the addition of alkali is not mentions on page 45 it does stat that the bacterium is removed y NaOH thereby enhancing the content of PHB.

With regard to claims 11-12, **Qing et al.** discloses the claimed invention except for the particular choice of solvent. However, it would have been obvious for one of ordinary skill in the art at the time the invention was made to employ either of the solvents as mentions since all are commonly employed in the art and since no such unobvious product results therefrom.

With regard to claim 13 **Qing et al.** discloses the claimed invention except for the particle range of particle diameter. However, it would have been obvious for one of ordinary skill in the art at the time the invention was made to produce an aggregate of PHA having particle diameter as claims since the reference does discloses a method for producing hot shaping polyhydroxyalkanoate polymers wherein on page 4 that the particles are typically of weight average diameter in the range of 0.1 to 5um, and form an aggregate at least 50, preferably 100-5000.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/23549 see claims; or USP 5213976 see col. 3 line 64 – col. 4 line 47, examples and claims; WO 97/07229 see abstract; or US Patent 6087471 see abstract and cols. 1-6. .

WO 97/23549 discloses the invention as follows:

This invention relates to processes for producing a shaped object of polyhydroxyalkanoate (PHA) that makes it possible to omit the preliminary extrusion-compounding step, thus saving expense and limiting loss of molecular weight. The process comprises producing a biomass containing particles of PHA and non-PHA cell material (NPCM), separating the NPCM, suspending the PHA particles in water, agglomerating the suspended PHA particles to a suitable weight average particle diameter, separating the agglomerated PHA particles from the suspension, drying the agglomerated PHA particles, and hot shaping the dry, agglomerated PHA particles. In one embodiment, the weight average particle diameter is 50 μm to 5000 μm. In another embodiment, a plasticiser is added to the agglomerated PHA particles.

USP 5213976 discloses a process for extracting polyhydroxyalkanoates from the cell material of microorganisms by adding an organic solvent for the polyhydroxyalkanoate

which is immiscible with water and which has a boiling point of below 100° C., and, if appropriate, by adding water; stirring the resulting extraction mixture, if appropriate with refluxing; separating off the aqueous phase which contains the cell material in undissolved form from the organic phase; and injecting the organic phase into hot water, causing the dissolved polyhydroxyalkanoate to precipitate and the organic solvent to evaporate, and also isolating the precipitated polyhydroxyalkanoate flocs.

WO 97/07229 which is disclosed as follows:

The present invention relates to a process for separating polyhydroxyalkanoate (PHA) from a biomass comprising the PHA, the process comprising: (a) treating the biomass with a PHA solvent and a marginal nonsolvent for PHA; (b) removing any insoluble biomass, thereby leaving behind a solution of PHA and marginal nonsolvent for PHA; and (c) removing the PHA solvent from the solution, thereby resulting in a suspension of precipitated PHA in the marginal nonsolvent for PHA. Optionally, the process further comprises removing the marginal nonsolvent for PHA, thereby leaving behind the PHA. The present invention further relates to the suspension and the PHA produced by the process.

US Patent 6087471 discloses a method of recovering PHA from biomass comprising: providing biomass containing PHA;dissolving the PHA with an effective PHA-poor solvent typically at a temperature above the boiling point of the PHA-poor solvent to produce PHA-enriched solvent and residual biomass materials; separating the residual biomass materials from the PHA-enriched solvent;
reducing the temperature of the PHA-enriched solvent such that PHA precipitation occurs; and recovering the precipitated PHA polymer.

An effective PHA-poor solvent comprises a non-halogenated solvent which preferably dissolves less than about 1% (w/v) of the PHA being extracted at a temperature less than the solvent boiling point. Suitable PHA-poor solvents can be selected from the group consisting of linear and branched R_1 --OH alcohols and R_2 --$COOR_3$ esters where R_1 =C_1 -C_4, R_2 =H or C_1 -C_3, and R_3 =C_1 -C_5. Examples of preferred PHA-poor solvents include methanol, ethanol, n-propanol, iso-propanol, and n-butanol.

The PHA is dissolved with a solvent mixture comprising a PHA-good solvent and a PHA-poor solvent at a temperature effective for dissolving the PHA, typically at a temperature above about 80° C. The PHA is then precipitated by reducing the temperature of the PHA-enriched solvent.

Suitable PHA-good solvents for use in this aspect of the invention can include

essentially any solvent effective for solubilizing the PHA of interest. Preferred PHA-good solvents are typically selected from the group consisting of cyclic and acyclic (linear and branched) R'--OH alcohols where R'=C_4 -C_{10}, cyclic and acyclic R"--COOR'" esters where R"=H or C_1 -C_6 and R'"=C_1 -C_7, cyclic and acyclic R"--COOR'" esters where R'=H or C_1 -C_6 and R'"=C_1 -C_7 and wherein at least one oxygen is substituted for at least one carbon in R" or R'", cyclic and acyclic R^1 --CON--$(R^2)_2$ amides where R^1 =H or C_1 -C_6 and R^2 =C_1 -C_6, and cyclic and acyclic R^3 --CO--R^4 ketones where R^3 =C_1 -C_6 and R^4 =C_1 -C_6.

Examples of preferred PHA-good solvents for use in the methods of the present invention include butyl acetate, isobutyl acetate, ethyl lactate, isoamyl acetate, benzyl acetate, 2-methoxy ethyl acetate, tetrahydrofurfuryl acetate, methyl propionate, propyl propionate, butyl propionate, pentyl propionate, butyl butyrate, isobutyl isobutyrate, ethyl butyrate, ethyl valerate, methyl valerate, benzyl benzoate, methyl benzoate, dimethyl succinate, dimethyl glutarate, dimethyl adipate, isobutyl alcohol, 1-butanol, 2-methyl-1-butanol, 3-methyl-1 butanol, 1-pentanol, 3-pentanol, amyl alcohol, allyl alcohol, hexanol, heptanol, octanol, cyclohexanol, 2-ethylhexanol, tetrahydrofurfuryl alcohol, furfuryl alcohol, benzyl alcohol, 2-furaldehyde, methyl isobutyl ketone, methyl ethyl ketone, g-butyrolactone, methyl n-amyl ketone, 5-methyl-2-hexanone, ethyl benzene, 1,3-dimethoxybenzene, cumene, benzaldehyde, 1,2-propanediol, 1,2-diaminopropane, ethylene glycol diethyl ether, 1,2,3-trimethylbenzene, 1,2,4-trimethylbenzene, 1,3-dioxane, 1,4-dioxane, 1-nitropropane, toluene-2,4-diisocyanate, acetic acid, acrylic acid, acetic anhydride, alpha-methylstyrene, acetophenone, toluene, ethylene glycol diacetate, dimethylsulfoxide and propylene carbonate, dimethyl acetamide, dimethyl formamide, or mixtures thereof.

Each of the references discloses a agglomerated poly-3- hydroxyalkanoic acid suspension prepared from the same components as claimed by applicants except for the particular range or points as noted in the specification (but not claimed).

However, it would have been obvious to one of ordinary skill in the art to envisage the limitations or range as claimed since such selection overlaps or falls within that which is disclosed since it is well-established that merely selecting proportions and ranges is not patentable absent a showing of criticality. In re Becket, 33 U.S.P.Q. 33 (C.C.P.A. 1937). In re Russell, 439 F.2d 1228, 169 U.S.P.Q. 426 (C.C.P.A. 1971). Generally, it is prima facie obvious to determine workable or optimal values within a prior art disclosure through the application of routine experimentation. *See* In re Aller, 105 USPQ 233, 235 (CCPA 1955); In re Boesch, 205 USPQ 215 (CCPA 1980); and In re Peterson, 315 F.3d 1325 (CA Fed 2003).

35 USC 112, Second Paragraph

Claims 1- 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants claims do not include what appears, according to the specification, the necessary parameters or conditions necessary to particularly point out the subject matter applicants intends as the invention. Note further that a process should at least recite a positive, active step and any process parameters necessitated by the specification so that the claim will "clearly set out and circumscribe a particular area with a reasonable degree of precision and particularity, In re Moore, 169 USPQ 236, and make it clear what subject matter the claim encompasses, as well as make clear the subject matter from others would be precluded. In re Hammack 166 USPQ 204.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the suspension of the poly-3-hydroxy alkanoic acid having a concentration as noted on page 7 does not reasonably provide enablement for any amount or degree of concentration or any temperature range. The specification does not enable any person skilled in the art to which it pertains, or with

which it is most nearly connected, to make any use the invention commensurate in scope with these claims.

Although the specification states that the suspension is not particularly restricted, the specification does note adverse effects if the concentration is too high. Similarly, on page 8 the specification notes that the temperature is preferably not less than room temperature…..not less than 60 C. It is noted that there are no examples or data in the tables showing temperatures other than those within the range above that result in a product having the improved characteristics as noted on pages 1-4 of the specification.

Although the CCPA has criticized the use of the characterization "too broad" or "undue breadth"....however, an application whose claim(s) are of a breadth which are not adequately supported by its specification is in violation of 35 USC 112, first paragraph. In re Borkowski et al., (CCPA 1970) 424 F2d 904; In re Wakefield, (CCPA 1970 422 F2d 897; In re Hammack, (CCPA 1970) 427 F2d 1378.

Case law holds that applicant's specification must be "commensurately enabling [regarding the scope of the claims]." See *Ex Parte Kung*, 17 USPQ2d 1545, 1547 (Bd. Pat. Appl. Inter. 1990). Otherwise **undue experimentation** would be involved in determining how to practice and use applicant's invention. The test for undue experimentation as to whether or not all compounds within the scope of claims 1-12 can be used as claimed and whether claims 1-12 meet the test is stated in *Ex parte Forman*, 230 USPQ 546, 547 (Bd. Pat. Appl. Inter. 1986) and *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Upon applying this test to claims 1-12, it is believed that undue experimentation **would** be required because:

(a) *The quantity of experimentation necessary* is **great** since claims 1-12 read on any type of concentration or temperature range such as those not disclosed by the specification.

((c) There is an **absence** *of working examples* concerning making an agglomerated poly-3-hydroxyalkanoic acid suspension comprising any type of concentration or temperature range such as those *not* disclosed by the specification.

In light of the above factors, it is seen that undue experimentation would be necessary to make and use the invention of claims 1-12.

Information Disclosure Statement

Note that any information disclosure must comply with 37 CFR § 1.98(b), which requires a list of the publications to include: the author (if any), title, relevant pages of the publication, *date* and place of publication to be submitted for consideration by the Office.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terressa M. Boykin whose telephone number is 571 272-1069. The Examiner can normally be reached Monday- Friday 9:30-6:00 (work at home).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 571 272-1078.

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